

Actual Use Study of a Heated Tobacco Product (glo™)

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OUTLINE

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- 3 Results
- 4 Conclusion



Objectives

Describe the acceptance of the HTP IP (i.e., glo™) and the pattern of CC consumption in the context of glo™ availability among current daily cigarette smokers.

PRIMARY ENDPOINT 1

Determine number and proportion of subjects who meet the definition of “established users” of glo™ (defined as using ≥ 100 neo sticks) over the 6 weeks of the AUP.

PRIMARY ENDPOINT 2

Determine number and proportion of subjects among “established users” who reduce their cigarettes per day (CPD) consumption by at least 50% at the end of the AUP.

PRIMARY ENDPOINT 3

Descriptive weekly average CPD consumption per subject among all subjects.

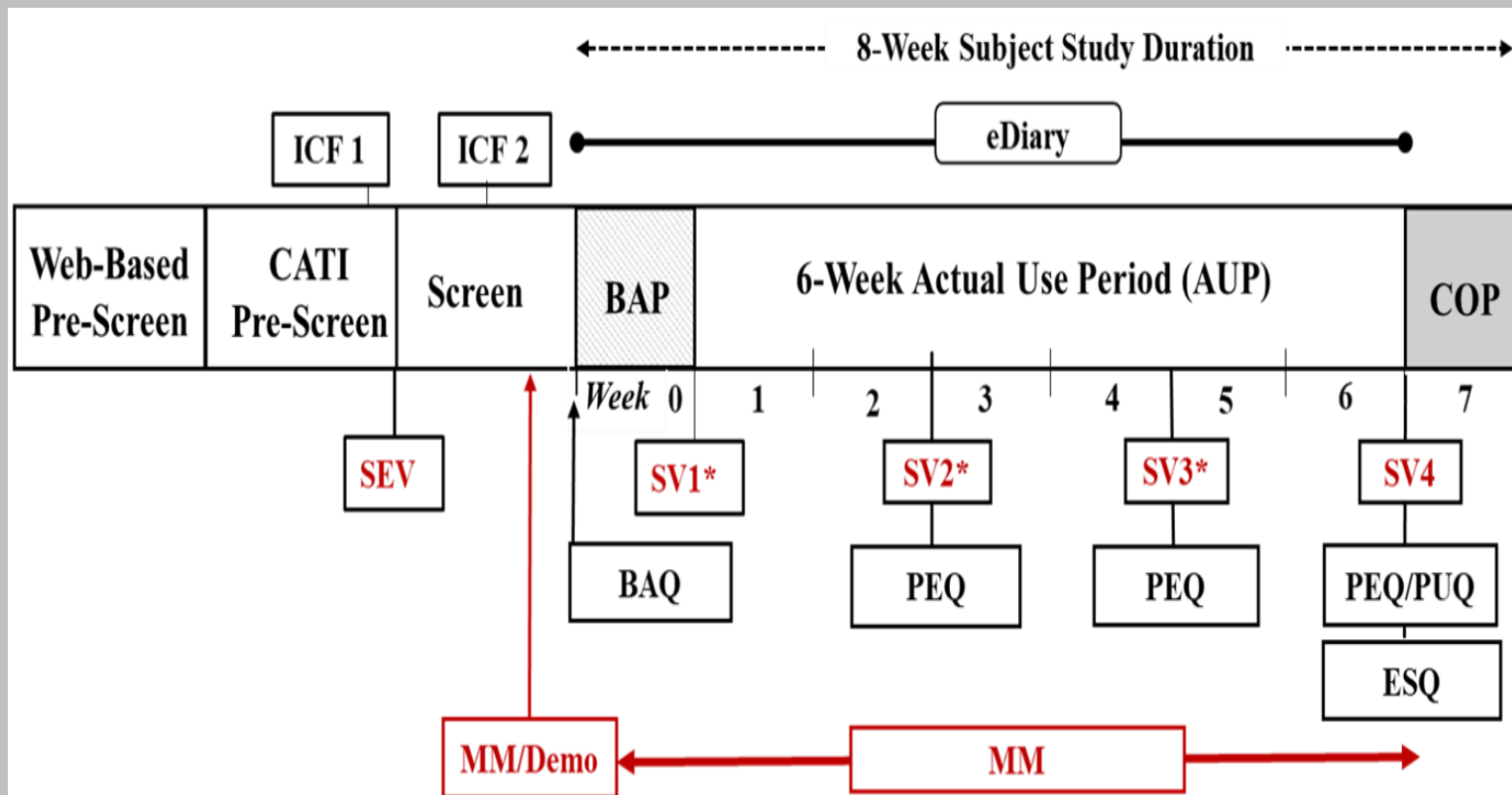
Methods & Study Design

Key Inclusion Criteria:

Adult smokers (defined as ≥ 5 CC/day, smoked 100 CC in lifetime and at least 20/30 days smoked in the past month). Must indicate “an intention to use” glo™ and able and willing to comply with all study requirements.

Study IP:

Heated Tobacco Product (glo glo™) is an alternative to combustible TNPs that can be used with non-combusted neosticks to heat rather than burn tobacco.



* Study IP Distribution

BAP = Baseline Assessment Period

BAQ = Baseline Assessment Questionnaire

CATI = Computer-Assisted Telephone Interview

ESQ = End-of-Study

COP = Close Out Period

ICF = Informed Consent Form

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MM = Marketing Materials

PEQ = Product Experience Questionnaires

PUQ = Product Use Questionnaire

SEV = Screening and Enrollment Visit

SV = Site visit

DEMOGRAPHICS

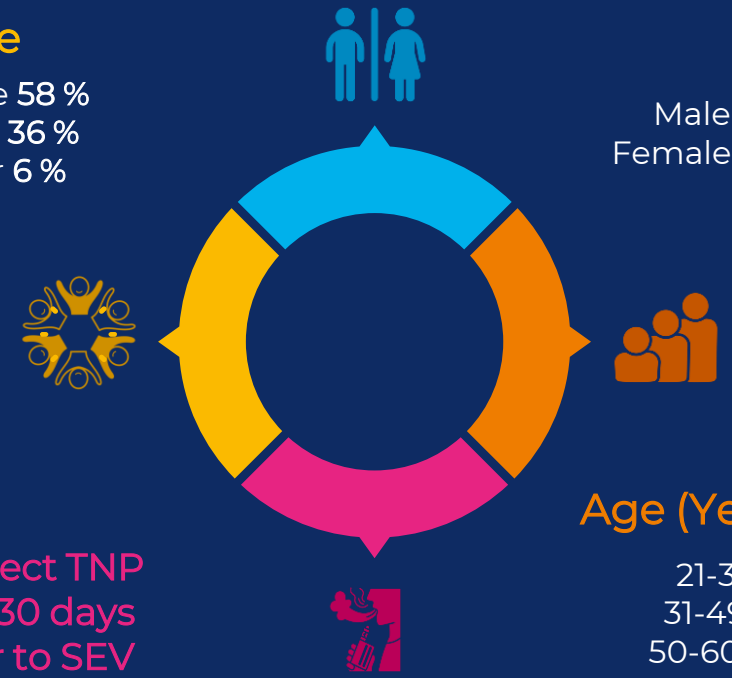


Race

White 58 %
Black 36 %
Other 6 %

Sex

Male 42 %
Female 58 %



Subject TNP Use 30 days prior to SEV

Poly CC and more than one other TNP 50.6 %
Exclusive CC 22.8 %
Dual CC and Vaping 16.8 %
Dual CC and Other Combustible Tobacco Products 8.8 %
Dual CC and Oral 0.7 %
Dual CC and HTP 0.2 %

Age (Years)

21-30 7 %
31-49 61 %
50-60 32 %

* 1229 subjects attended the SEV, 49 screen fails occurred
** 60 enrolled subjects not included in the FAS as did not meet the criteria
*** 47 subjects were terminated early mainly due to lost to follow-up, followed by non-compliance with eDiary

COMPLIANCE RATES

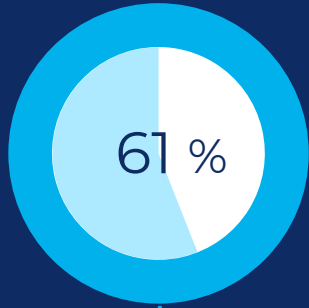
Numbers of Subjects fulfilling compliance criteria	n (%)
Number of subjects with eDiary entries available for at least 6 days of the one-week baseline period	1094 (97.7 %)
Number of subjects with eDiary entries available for at least 6 days per week during the six-week Actual Use Period	877 (78.3 %)
Number of subjects who did not miss any Site Visit	1014 (90.5 %)

SAFETY REPORTING

Less than 1%
of subjects
reported
an AE

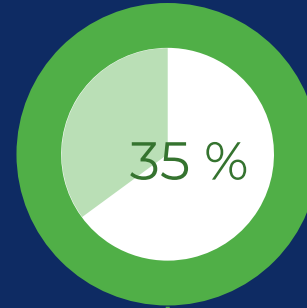


Primary Endpoints



PROPORTION OF ESTABLISHED USERS OF GLO™

660 subjects met the definition of established users* of glo™ by Week 6



50 % CPD CONSUMPTION REDUCTION

236 established users of glo™ reduced their CPD consumption by at least 50% or more by Week 6



AVERAGE CPD REDUCTION

Average CPD of all completed subjects (n=1073) decreased from 12.4 at baseline to 8.99 at Week 6

* Established users defined as using ≥ 100 neo sticks over AUP.

Note: Results are based on preliminary data

GLO™ USE

4.5 Neo Sticks Per Day at Week 6 (All Completed Subjects)
6.8 Neo Sticks Per Day at Week 6 (Established Users)

INTENT TO USE GLO™ AGAIN

Subjects were asked about their intent to use glo™ again at the end of the study on a scale of 1-10 (1 being definitely would not use it and 10 being definitely would use).

- ❑ 573 subjects (53.4 %) reported they would use it again (6-10).
- ❑ 130 subjects (12.1 %) reported they would 'definitely use it again'.

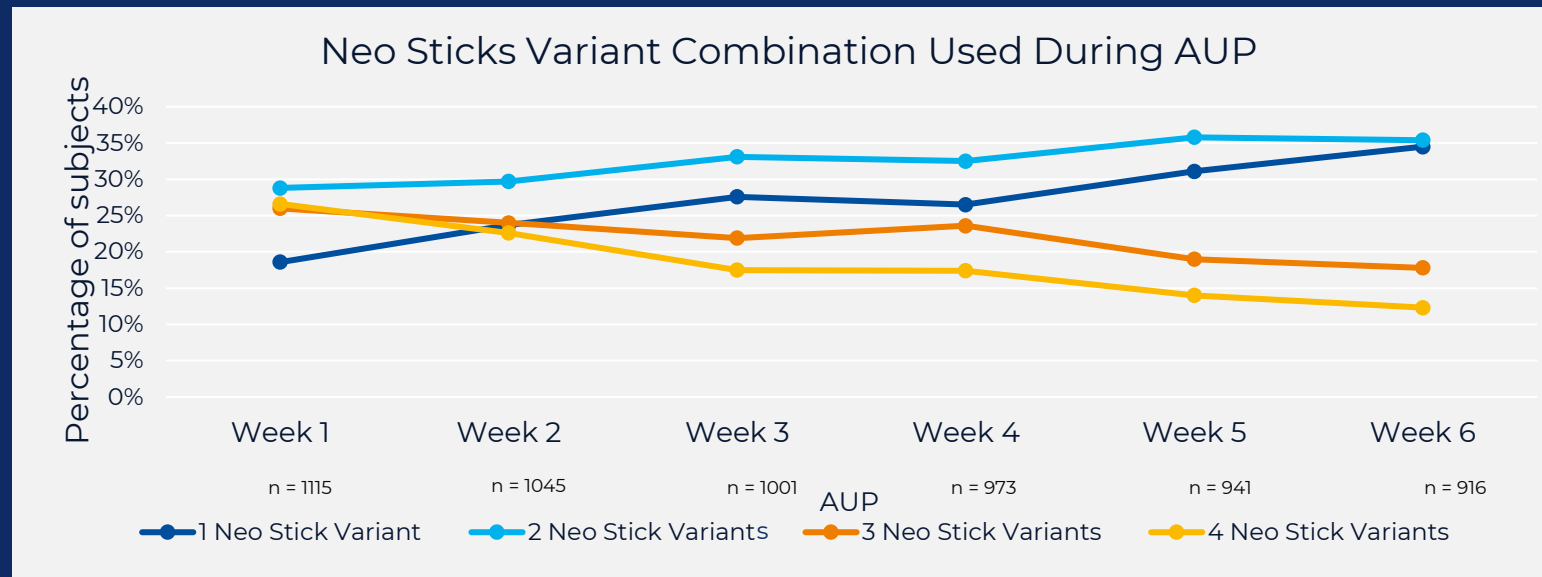
COMPLETELY QUIT CC

- ❑ 41 subjects (3.8 %) reported to have completely quit CC at the end of the study
- ❑ 34 subjects (3.2 %) were exclusively using glo™ at the end of the study

NEO STICK USE

NEO STICK USE

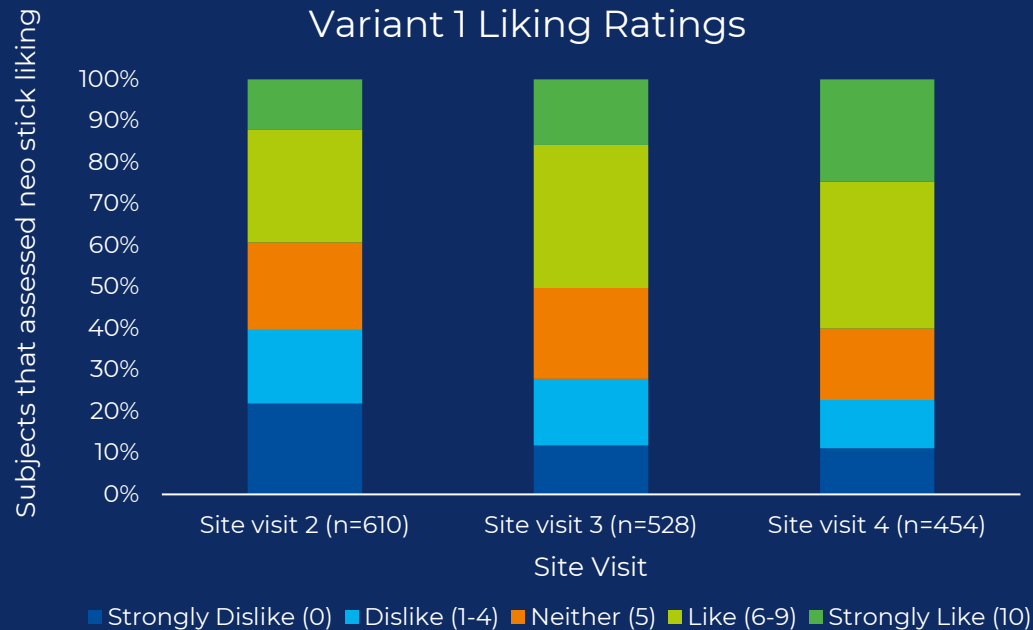
- By Week 6, the use of all 4 variants was evenly distributed
- By Week 6, most subjects used 1 or 2 neo stick variants (compared to 2, 3 and 4 neo stick variants at week 1)



PRODUCT USE EXPERIENCE

NEO STICKS LIKING

- ❑ Positive liking rates increased over AUP
- ❑ Consistent across all four neo stick variant types



GLO™ MISUSE

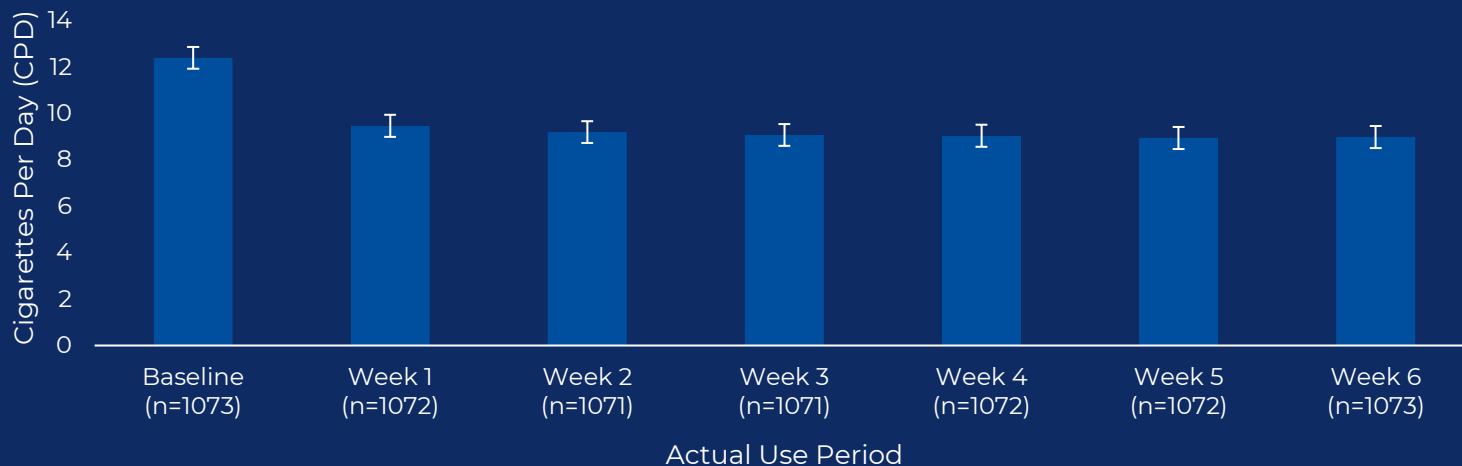
615 subjects reported using the product in a manner that differs from product use instructions

Most frequent glo™ Misuse:

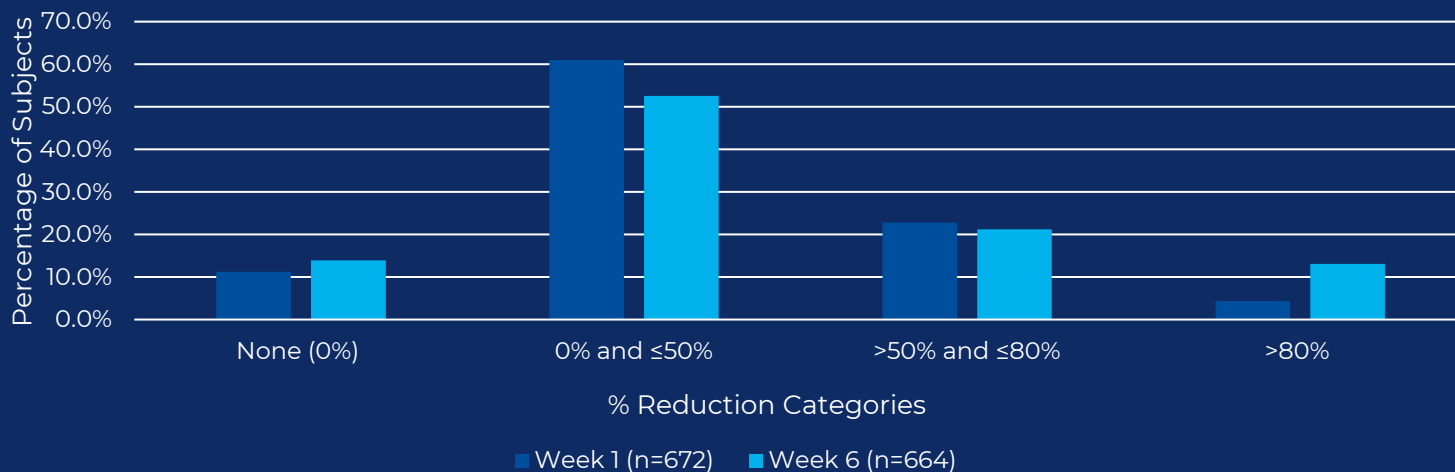
- ❑ Left glo unattended while charging
- ❑ Reuse of neo stick
- ❑ Tried to light and smoke a neo stick

CC CHANGE FROM BASELINE

CPD Over Time of all Study Completers



CC Reduction Over Time of Established Users



CIGARETTE USE CHANGE FROM BASELINE

All Study Completers

- Mean CPD decreased during AUP
- By Week 6 CPD reduction was 29 %

All Completers & Established Users of glo™

- ~20 % of all completers and ~14 % of established users did not reduce at all
- ~50 % of all completers and established users reduced up to 50%
- ~24 % of all completers and ~34 % of established users reduced more than 50 %

Conclusions

- 61 % of participants became established users of glo™
- 35 % of established users reduced their CC consumption by ≥ 50 %
- On average, CC consumption was reduced by 29 %
- neo stick variants were rated highly on the liking scale
- High compliance rates (eDiary completion and site visit rates)
- Low attrition rate (4 %)
- Low AEs reported (<1 % subjects)
- glo™ has the potential to positively impact public health
- Study results have informed the acceptance of glo™ and CC consumption patterns



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Thank you. Any Questions?